



SEP 16 1992

Memorandum

Date

From

Thomas D. Rozlewicz
Bryan B. Mitchell
Principal Deputy Inspector General

Subject

Audit of Six Ulcer Treatment Drugs Reimbursed Under the Minnesota Medicaid Prescription Drug Program (A-06-92-00005)

To

William Toby, Jr.
Acting Administrator
Health Care Financing Administration

This is to alert you to the issuance on September 17, 1992, of our final report. A copy is attached.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires State Medicaid agencies to operate drug use review programs on an ongoing basis. These programs are intended to assess actual patient drug use against predetermined standards. One of the standards recognized by OBRA '90 is the manufacturers' recommended dosages.

The manufacturers of six ulcer treatment drugs provide recommendations for the prescribing of their drug products in the treatment of gastric and duodenal ulcers. The Minnesota Department of Human Services (State agency), however, did not have any restrictions pertaining to the manufacturers' recommended dosages for ulcer treatment drugs. Accordingly, our review showed that about \$2.03 million (Federal share \$1.07 million) in cost savings could have been realized for Calendar Year 1990 had the State agency limited payment for these drugs to the amount needed to pay for the manufacturers' recommended dosages.

We are recommending that the State agency establish procedures to limit the payment for these ulcer treatment drugs to the manufacturers' recommended dosages. We believe that the Health Care Financing Administration (HCFA) should take an active role in encouraging the State agency to implement our recommendation.

In a letter dated April 6, 1992, the Assistant Commissioner for the Minnesota Department of Human Services indicated that the State agency would take our recommendations under advisement and review them with the Minnesota Drug Utilization and Review Board.

Page 2 - William Toby, Jr.

Because ulcer treatment drugs are among the most commonly prescribed Medicaid drugs, we are performing this review at eight randomly selected States to quantify the potential cost savings available nationwide to the Medicaid program by limiting the reimbursements for these drugs to the manufacturers' dosage. When we have completed our reviews of the remaining States, we will be issuing a consolidated report to HCFA on this subject.

For further information, contact:

Donald L. Dille
Regional Inspector General
for Audit Services, Region VI
(214) 767-8414

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF SIX ULCER TREATMENT
DRUGS REIMBURSED UNDER THE
MINNESOTA MEDICAID PRESCRIPTION
DRUG PROGRAM**



SEPTEMBER 1992 A-06-92-00005



Office of Audit Services
1100 Commerce, Room 4E1A
Dallas, TX 75242

Our Reference: Common Identification No. A-06-92-00005

Natalie Hass-Steffen, Commissioner
Minnesota Department of Human Services
444 Lafayette Road
St. Paul, Minnesota 55155-3853

Dear Ms. Hass-Steffen:

This report provides you with the results of our audit of six ulcer treatment drugs reimbursed under the Medicaid prescription drug program of the Minnesota Department of Human Services (State agency). The objective of our audit was to determine the extent that ulcer treatment drugs were paid for by the Medicaid program in dosages that exceeded the manufacturers' recommended dosages.

The State agency has an opportunity to implement procedures to limit payments for the six ulcer treatment drugs to the manufacturers' recommended dosages. We found that the recommended dosages were exceeded in 82 of the 200 sampled cases. We estimate that implementing procedures based on manufacturers' recommendations could result in savings of about \$2,029,916 (Federal share \$1,074,029).

We believe that the implementation of such a program can be cost effective in Minnesota. For example, the State of Texas has already set up a prospective drug use review (DUR) system at a cost of about \$180,000 and has estimated first year savings of \$6 million for its ulcer treatment drugs. Therefore, we are recommending that the State agency implement procedures to limit payment for the six ulcer treatment drugs to the amount needed to pay for the manufacturers' recommended dosages.

The Assistant Commissioner for the Minnesota Department of Human Services responded to our draft report in a letter dated April 6, 1992. The Assistant Commissioner stated that the State agency would take our recommendations under advisement and review them with the Minnesota Drug Utilization and Review Board. Further, he indicated that one of the ulcer treatment drugs now requires prior authorization when usage exceeds 8 weeks of treatment. The full text of the Assistant Commissioner's comments are included as **Appendix C** to this report.

BACKGROUND

Medicaid is a federally-aided, State operated and administered program that provides medical benefits to low income persons who are aged, blind, disabled, or members of families with dependent children where one parent is absent, incapacitated, or unemployed. The program, authorized by title XIX of the Social Security Act, requires States to provide certain medical services and permits them to provide other services, such as outpatient prescription drugs, on an optional basis. Federal oversight is the responsibility of the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS).

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires State Medicaid agencies to operate DUR programs on an ongoing basis. These programs are intended to assess actual patient drug use data against predetermined standards which are contained in the compendia listed in OBRA '90.

Tagamet, Zantac, Pepcid, and Axid belong to a classification of drugs known as histamine H₂-receptor antagonists (or H₂ antagonists). These drugs are prescribed for the treatment of gastric and duodenal ulcers and have reduced the need for stomach ulcer surgery. Unlike earlier drugs which tried to neutralize excess stomach acid, these drugs reduce the actual flow of acid. Carafate and Prilosec (formerly Losec) are not H₂ antagonists, but they are related ulcer treatment drugs and are prescribed in a similar manner.

Pharmaceutical publications such as **Facts and Comparisons** and **Physician's Desk Reference**, as well as prescribing and product information (package inserts) published by the manufacturers, provide information concerning recommended dosages for these drugs. These resources show that the manufacturers recommend that these drugs be prescribed in full dosages during an active treatment period of 4 to 8 weeks to promote healing of the ulcer. After the active treatment period, the manufacturers recommend that the dosages be reduced by 67 percent for Tagamet and 50 percent for Zantac, Pepcid, Axid, and Carafate as maintenance therapy to prevent recurrence. No maintenance therapy is recommended for Prilosec. These resources did not clearly define the manufacturers' recommendations regarding the length of the maintenance therapy period.

There are circumstances in which the maintenance level dosages are inappropriate. For example, the drugs are used in the treatment of pathologic gastrointestinal hypersecretory conditions or "Zollinger-Ellison syndrome." According to available literature, treatment of this rare disease with H₂ antagonists continues for as long as clinically necessary with no active or maintenance treatment periods.

Limiting the prescribing of these drugs to the medically necessary dosages recommended by the manufacturers offers potential cost savings because of the drugs' popularity and price. In recent years, Zantac and Tagamet have ranked as the top two drugs in terms of sales revenue among drugs sold worldwide and ranked in the top five in terms of sales revenue in the United States market. Using the average wholesale price, a 30-day supply of these drugs at active dosage levels costs from \$60 to \$120.

SCOPE

The objective of our audit, which was conducted in accordance with generally accepted government auditing standards, was to determine the extent that ulcer treatment drugs were paid for by the Medicaid program in dosages that exceeded the manufacturers' recommended dosages. Achieving our audit objective did not require that we review the entire internal control structure of the State agency. Therefore, we reviewed only those controls relating to the utilization of the ulcer treatment drugs selected for review.

To accomplish our objective, we reviewed various drug compendia including, **Facts and Comparisons, Physician's Desk Reference, American Hospital Formulary Service, and United States Pharmacopeial Drug Information** regarding manufacturers' recommended dosages and strengths for the drugs selected for review. We also examined product information (package inserts) for the drugs.

The State agency's computerized Medicaid prescription drug payment records contained 25,980 unduplicated Medicaid recipients who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec during Calendar Year (CY) 1990. Of these, we randomly selected a sample of 200 recipients. Our review was performed during the period October 1991 through February 1992.

Our review did not include an evaluation of the medical necessity of dosages for ulcer treatment drugs received by the 200 sample Medicaid recipients. Therefore, our savings estimate did not consider those situations where manufacturers' recommended dosages for the drugs were exceeded due to medical necessity. Additionally, the savings estimate did not consider increases due to inflation and program growth since 1990.

RESULTS OF AUDIT

The State agency has an opportunity to implement procedures to limit payments for the six ulcer treatment drugs to the manufacturers' recommended dosages. Although the manufacturers recommended that dosages be reduced by 50 percent to 67 percent after a 4 to 8 week active treatment period, we found that the

recommended dosages were exceeded in 82 of the 200 sampled cases. We estimate that implementing procedures based on manufacturers' recommendations could result in savings of about \$2,029,916 (Federal share \$1,074,029).

The State of Minnesota did not have a program in place to limit payment for the six ulcer treatment drugs to the manufacturers' recommendations. We believe that the implementation of such a program can be cost effective in Minnesota. For example, the State of Texas has already set up a prospective DUR system at a cost of about \$180,000 and has estimated first year savings of \$6 million for its ulcer treatment drugs. In response to an Office of Inspector General (OIG) audit, the State of Arkansas agreed that ulcer treatment drugs were overprescribed and overutilized and implemented a cost containment program for ulcer treatment drugs. Therefore, we are recommending that the State agency implement procedures to limit payment for the six ulcer treatment drugs to the amount needed to pay for the manufacturers' recommended dosages.

MINNESOTA'S CURRENT PROCEDURES

A State agency official advised us that there were no procedures in place to limit reimbursements for these drugs. The official stated that there had been some effort to educate physicians about manufacturers' recommendations for ulcer treatment drugs.

We believe that Minnesota should implement a program to limit payments for ulcer treatment drugs to the amount needed to pay for the manufacturers' recommended dosages. The limitation should not be imposed in cases where continued active treatment is necessary based on physicians' authorizations of medical necessity. Payments should be denied, however, for active treatment dosages that extend beyond the active treatment period for claims that are not supported by physicians' statements of medical necessity.

RESULTS OF REVIEW OF A SAMPLE OF MEDICAID RECIPIENTS TO DETERMINE POTENTIAL COST SAVINGS

The State agency's computerized Medicaid prescription drug payment file contained 25,980 unduplicated Medicaid recipients who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec during CY 1990. Of these, we randomly selected a sample of 200 recipients and found that dosages were not always reduced when the period of active treatment ended and the maintenance therapy began. In addition, there were 12 instances where the active treatment dosages exceeded the manufacturers' recommended dosages. In summary, 82 of the 200 Medicaid recipients in the sample received dosages that exceeded the manufacturers' recommended dosages. The remaining 118 recipients in the sample received dosages equal to or lower than

the manufacturers' recommended dosages. (See **Appendix A** for a description of our sampling methods.)

The total amount paid by Medicaid on behalf of the 200 sampled recipients for the drugs was \$70,280. The applicable potential cost savings for the 200 recipients was \$15,627 or about 22 percent of the Medicaid paid amount. Using this data, the estimated annual savings would have been about \$2,029,916 (Federal share \$1,074,029) if Minnesota had limited dosages to the manufacturers' recommended dosages. (See **Appendices** for computation of our sample results.)

In calculating the potential cost savings, we determined the difference between the number of tablets paid for and the number of tablets recommended by the manufacturers for each prescription. Then we multiplied this difference (number of tablets) by the drug price per tablet paid by Medicaid for the prescription. This calculation was made for both active and maintenance treatment periods. The results were combined into one potential cost savings amount for the sampled recipients.

The manufacturers' recommended daily dosages, which we used in our calculations, are shown as follows:

<u>DRUG</u>	<u>ACTIVE CONDITIONS</u>	<u>MAINTENANCE THERAPY</u>	<u>REDUCTION IN DOSAGE</u>
Tagamet	1200 mg	400 mg	67%
Zantac	300 mg	150 mg	50%
Pepcid	40 mg	20 mg	50%
Axid	300 mg	150 mg	50%
Carafate	4 g	2 g	50%
Prilosec	20 mg	None	100%

Since these drugs are packaged in several different strengths, we determined the total number of tablets needed to equate to the recommended dosage levels. For example, if a physician prescribed Tagamet in 400 mg tablets, the number of tablets per day allowed in our calculations would be 3 (1200 mg divided by 400 mg) for active treatment or 1 (400 mg divided by 400 mg) for maintenance therapy.

We reviewed the manufacturers' recommended active treatment periods for various illnesses and concluded that a maximum of 8 weeks would be appropriate since, except for special circumstances, it represents the maximum active treatment period for the drugs. Therefore, in our calculations we used 62 days (the maximum number of days in a 2-month supply) as the applicable active treatment period. We believe that this period is reasonable because for certain illnesses the manufacturers recommended shorter active treatment periods. For example, the

manufacturer of Tagamet states in its prescribing information bulletin (TG:L83) regarding treatment of active duodenal ulcer, "...while healing with Tagamet often occurs during the first week or two, treatment should be continued for 4-6 weeks unless healing has been demonstrated by endoscopic examination."

We allowed one active treatment period for each different drug received by the Medicaid recipients. We started the count of days for determining the active treatment period on October 1, 1989, 3 months prior to the beginning of our review period. By doing so, we were able to determine whether a recipient receiving one of the drugs in the first month of our review period had already completed the active treatment. We restarted the count of days for determining an active treatment period if there was a break in treatment of 30 days or more before completing the active treatment period. We recognize that in special circumstances the active treatment period could extend beyond 62 days. For purposes of this study, however, we did not consider such special cases.

With regard to the maintenance treatment period, we did not set any limitations on the number of days, because there were no clearly defined manufacturers' recommendations regarding the termination of maintenance therapy.

ULCER TREATMENT DRUG LIMITATION PROGRAMS IN TWO STATES

The State of Texas has a program for ulcer treatment drugs which has produced significant savings consistent with good medical practice. Under the program, Medicaid recipients are limited to acute dosage levels of ulcer treatment drugs for up to 62 days. The dispensing pharmacist is able to determine whether a recipient has reached or exceeded the end of a 62 day active treatment period by calling a toll-free 800 number (using a touch-tone phone) directly linked to the profile data for each recipient. Texas State agency officials estimated that the personal computer based voice response system, that cost approximately \$180,000, saved the Medicaid program approximately \$6 million during State Fiscal Year 1991.

The physicians are able to override the 62 day active treatment limit for higher dosage levels by writing the diagnosis on the face of a prescription. The pharmacist must submit a copy of the prescription to be reimbursed.

We performed a similar audit of ulcer treatment drugs within the Arkansas Medicaid program for CY 1989. Our audit showed the potential for cost savings of about \$1.27 million (Federal share \$940,594) by limiting reimbursement to the manufacturers' recommended dosages. The Arkansas audit was limited to Tagamet, Zantac, and Pepcid.

The Administrator of the Arkansas Pharmacy Program agreed with the findings of our audit and indicated that the ulcer treatment drugs were overprescribed and overutilized. The Administrator advised that the State was implementing a cost containment program for ulcer treatment drugs and that the State planned to have a prospective review program by January 1993.

RECOMMENDATIONS

We recommend that the State agency implement procedures to limit the payment for all ulcer treatment drugs to the amount needed to pay for the manufacturers' recommended dosages.

AUDITEE COMMENTS

The Assistant Commissioner for the Minnesota Department of Human Services responded to our draft report in a letter dated April 6, 1992. The Assistant Commissioner stated that our recommendations would be taken under advisement and reviewed by the Minnesota Drug Utilization and Review Board. The Assistant Commissioner also commented on specific portions of the report.

Specifically, the Assistant Commissioner considered the Texas system described in our report more as prior authorization rather than a DUR program and was accordingly focused on specific drugs rather than being a comprehensive review program. The Assistant Commissioner indicated that our savings estimate was overstated, because medically necessary cases were not taken into account. The Assistant Commissioner also was concerned that our sample size was not statistically significant to replicate the experience of 25,000 cases. Finally, the Assistant Commissioner advised that as of March 1, 1992, the ulcer treatment drug, Prilosec requires prior authorization when usage exceeds 8 weeks of treatment.

OIG RESPONSE

We agree that the Texas system for ulcer treatment drugs is a prior authorization program for specific drugs. However, we believe that a prior authorization program is an important and effective part of a comprehensive drug restriction program.

We stated in the **Scope** section of our report that we did not evaluate the medical necessity of dosages received by the 200 sample Medicaid recipients. We agree that the cost savings estimate would be more accurate if the recipients receiving excessive dosages for medically necessary reasons were eliminated. However, we believe that our estimates of potential savings are representative.

Page 8 - Ms. Natalie Hass-Steffen

We selected our sample size of 200 Medicaid recipients in accordance with our Office of Audit Services (OAS) policy and generally accepted statistical sampling principles. The results of our sample indicate a more than adequate sample size.

We believe that the State agency's recently imposed prior authorization for Prilosec after 8 weeks usage is consistent with the recommendations of our report.

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Final determination as to actions to be taken on all matters reported will be made by the HHS official named below. We request that you respond to the recommendations in this report within 30 days from the date of this letter to the HHS official named below, presenting any comments or additional information that you believe may have a bearing on his final decision.

In accordance with the principles of the Freedom of Information Act (Public Law 90-23), OIG, OAS reports issued to the Department's grantees and contractors are made available, if requested, to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.)

To facilitate identification, please refer to the above common identification number in all correspondence relating to this report.

Sincerely,



DONALD L. DILLE
Regional Inspector General
for Audit Services

Direct Reply To:

Associate Regional Administrator
Division of Medicaid
Health Care Financing Administration
Region V, Department of Health
and Human Services
15th Floor, 105 West Adams Street
Chicago, IL 60603

APPENDICES

SAMPLE DESCRIPTION

Sample Objective:	Project potential cost savings for excess Medicaid drug utilization attributable to Minnesota Medicaid recipients who received the ulcer treatment drugs Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec for CY 1990.
Sample Information:	Total expenditures for the Minnesota Medicaid outpatient prescription drug program were about \$75 million during the period January 1, 1990 through December 31, 1990.
Population:	The sampling population was 25,980 unduplicated Medicaid recipients who received Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec during the 12-month period ending December 31, 1990.
Sample Design:	Simple random sampling was used to select the sample items.
Sample Size:	A sample of 200 Medicaid recipients who received Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec.
Source of Random Numbers:	The OAS Statistical Sampling Software was used to determine the random numbers for drawing the sample.
Characteristics to be Measured:	From our examination of the Minnesota Medicaid payment history tapes, we calculated the per tablet price for each prescription received by the Medicaid recipients in our sample. When the dosages and/or duration of treatment exceeded the manufacturers' recommendations, we computed a dollar value for the excess drugs used. This value was used to determine the cost savings that would have been realized if there had been a control in place to limit payments for Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec tablets to the manufacturers' recommended dosages and durations of treatment.

Other Evidence: None.

Extrapolation: The total amount paid by Medicaid on behalf of the 200 sampled recipients for the 6 drugs was \$70,280. The potential cost savings for the 200 recipients was \$15,627 or about 22 percent of the Medicaid paid amount. Using this data and a 90 percent confidence level, the lower limit for our savings estimate was \$1,569,035, the upper limit was \$2,490,797, and the mid-point estimate was \$2,029,916.

APPENDIX B

SAMPLE RESULTS	
Sample Population (Unduplicated Medicaid recipients receiving Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec during CY 1990)	25,980
Standard Sample Size	200
Number of Sample Recipients Receiving Dosages in Excess of the Manufacturers' Recommended Dosages	82
Value of Sample	\$70,280
Total Value of Dosages in Excess of Manufacturers' Recommendations	\$15,627
Total Adjusted Value of Sample	\$54,653
At the 90 percent confidence level: Upper Limit Lower Limit	\$2,490,797 \$1,569,035
Estimated Total Annual Savings	\$2,029,916
Federal Share	\$1,074,029



State of Minnesota
Department of Human Services

Human Services Building
444 Lafayette Road
St. Paul, Minnesota 55155

April 6, 1992

Mr. Donald L. Dille
Regional Inspector General
for Audit Services
HHS/OIG Office of Audit Services
1100 Commerce, Room 4E1A
Dallas, Texas 75242

Re: Draft of HHS/OIG Report Common Identification
Number A-06-92-00005

Dear Mr. Dille:

In response to the above draft report and your letter of February 25, 1992, we are submitting the following comments for your consideration in preparation of the final report entitled, "Audit of Six Ulcer Treatment Drugs Reimbursed Under the Medicaid Prescription Drug Program: Minnesota Department of Human Services."

As mandated by OBRA 1990, Minnesota developed a Drug Utilization Program intended mainly to educate prescribers and providers. In preparation for the program, related issues were examined and guidelines for standards of practice were developed. Based on these guidelines, patients who were under review were profiled and the information sent to each provider for review and re-evaluation. These data will be summarized in April to assess the program intervention.

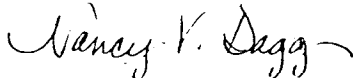
1. Your report references the Texas system for H2 antagonist on page 6. Minnesota views the Texas system more as prior authorization than DUR. The Texas system works only for certain drugs with certain conditions; it is not representative of a DUR program.
2. Regarding the "review of a sample of Medicaid recipients to determine potential cost savings," page 4: This estimate of savings is over-stated for the following reasons:
 - A. Medically necessary cases were not taken into account. The Texas system should be reviewed to determine the percentage of override cases due to medical necessity.
 - B. A sample size of 200 cases is not statistically significant to replicate the experience of 25,000 cases.

Mr. Donald L. Dille
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3. In Minnesota, as of March 1, 1992, prilosec requires prior authorization when usage exceeds eight weeks of treatment.

Thank you for the opportunity to provide input into the final audit report. We will take the IOG recommendations in this report under advisement and review them with the Minnesota Drug Utilization and Review Board.

Sincerely,



Nancy V. Dagg
Assistant Commissioner
Health Care Administration

cc: Charles W. Hazlett, HCFA, Region V
Robert Baird
Michael Miller
Linda Webster